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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,149	07/12/99	THORPE	P 4001.002383

HM12/0509

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EXAMINER	
SHARAREH,S	
ART UNIT	**PAPER NUMBER**
1616	8

DATE MAILED: 05/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/351,149	Thorpe et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

☒ Responsive to communication(s) filed on *Feb 7, 1900*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-43* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-43* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-43 are pending. Applicant's election of Group I Paper No. 6, and the nuclear magnetic isotopes as the elected species is acknowledged. However, the provisional election made on Paper No. 6 filed on February 7, 2000 is not fully responsive to the communication filed on January 19, 2000, because the elected species is not recited within the claims of the elected invention. Therefore, in view of Applicant's arguments, the Examiner has regrouped the previous restriction requirement to expedite the prosecution of instant application.

Response to Arguments

Applicant's traversal is on the basis that claim 1 is a linking claim which properly joins the imaging and combined cancer treatment aspects of the overall invention and thus the targeting agent-detectable agent construct and the second anti-cancer agents are encompassed within a generic invention. Applicant further asserts that the instant claims rather than being distinct are at best, separate species within a proper generic invention, and that Patent Office has not provided reasoning adequate to show that the invention of Group I through III are properly restrictable or distinct.

In view of Applicant's traversal, Examiner has reconsidered the previous restriction requirement and has modified the previous requirement as is presented below. However, Examiner would like to address the followings issues in response to Applicant's arguments.

The question in the instant restriction requirement is whether the instant kits comprising said targeting- therapeutic construct in combination with either a targeting-detectable construct or a second anti-cancer agent are patentably distinct kits when comprise additional therapeutic or

diagnostic compositions. It is clearly inferred from the claims that for example utilizing a second targeting-detectable construct constitute an additional imaging step which is patentably distinct when compared to utilizing a second anticancer composition alone or in combination, therefore, kits used for such distinct methods comprise distinct ingredients and thus differ from each other. Also, Applicant has not provided any evidence or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case.

Accordingly, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32, 43 drawn to kits comprising at least one targeting-therapeutic construct attached to a targeting agent-detectable agent construct or at least a second anti-cancer agent, classified in class 530, subclass 388.8+.

II. Claims 33-37, drawn to an imaging kit comprising two separate pharmaceutical compositions, classified in class 424, subclass 1.11+.

III. Claims 38-42, drawn to a kit for treatment of cancer having a second therapeutic or targeting agent, classified in class 514, subclass 2.

1. Inventions I and II or III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because kits for treatment of tumors does not require a diagnostic construct or a second

anti-cancer agent. The subcombination has separate utility such imaging the localized region of a vascularized tumor. Further, kits that are utilized for imaging with or without a second anti-cancer agent need materially different products, process steps and possess distinct endpoints.

2. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable see MPEP § 806.05(d). In the instant case, invention II has separate utility such as imaging a localized region of a vascularized tumor. Clearly one skilled in the art could readily practice the invention II without practicing invention III, since kits that are used for diagnostic methods are clinically independent from kits that are used for therapeutic purposes. Further each invention utilize different methods of practice.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for each Group I is not required for the others, restriction for examination purposes as indicated is proper.

This application contains claims that are drawn in Markush format and are directed to the following patentably distinct species of the claimed invention:

I) Kits comprising targeting agents directed to an specific protein or two binding ligand (claims 1-3, 43.)

II) Kits comprising at least a first antibody or antigen-binding fragment thereof (claims 1, 4-9, 33-36, 43.)

III) Kits comprising at least a first aminophospholipid binding protein or an aminophospholipid-binding fragment thereof (claims 1, 10-13, 43.)

IV) Kits comprising at least a first anticellular or cytotoxic agent (claims 1, 14-15, 43.)

V) Kits comprising at least a coagulant (claims 1, 16-18, 43.)

VI) Kits comprising a targeting agent-detectable agent, wherein detectable agent comprise X-ray compounds or radioactive ions or nuclear magnetic agents (claim 1, 20-23, 43.)

VII) Kits comprising at least a second anti-cancer agent (claims 1, 24-31, 37-38, 40, 43.)

In the event that the Markush-type claims are not found to be allowable, the examination of the claims presented will be limited to the Markush-type claims to the extent that they read on the elected species and claims directed solely to the elected species. The claims directed solely to the non-elected species will be held withdrawn from consideration.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species from the elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, if elected Group II Applicant is required to elect a single disclosed species for the specific diagnostic agent (an X-ray, a radionuclide or a detectable nuclear magnetic spin resonance isotope), a specific targeting agent including the specific first or second antibody (claims 33-36) and a specific first and second therapeutic agent that is attached to the targeting agent (claims 33, 37).

Currently, claims 1, 33, 38, 42-43 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 5/4/2000

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616